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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/989,881	12/12/97	SHEEN J	08472/716002

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EXAMINER	
ZAGHMOUT, O	

ART UNIT	PAPER NUMBER
1649	12

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/989,881	Sheen
Examiner	**Group Art Unit**
Ousama Zaghmout	1649

☒ Responsive to communication(s) filed on *Jul 28, 1999*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-48* is/are pending in the application.

Of the above, claim(s) *8-23, 27-35, 47, and 48* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-7, 24-26, and 36-46* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *6, 7*

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

L. F. Smith

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED OFFICE ACTION

Claims 1-48 are pending.

Claims 1-7, 24-26, 36-46 have been elected without traverse by Applicant. Subsequently, non- elected claims 8-23, 27-35, 47-48 were withdrawn from further consideration on the merit.

A copy of the signed IDS (1449 form) is enclosed

Notice of draftsperson's patent drawing review (PTO 948) is enclosed.

Claim Rejections-35 U.S.C. 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claim 36 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The DNA molecule, as claimed, has the same characteristics and utility as those found naturally in the genome or as cellular precursors thereof and therefore does not constitute patentable subject matter. See *American Wood v. Fiber disintegrating Co.*, 90 U.S. 566 (1974), *American Fruit Growers v. Brogdex Co.*, 283 U.S. 2 (1931), *Funk Brothers Seed Co. V. Kalo Inoculant Co.*, 33 U.S. 127 (1948), *Diamond v. Chakrabarty*, 206 USPQ 193 91980).

Amendment of the claim to insert the word --isolated-- before the the word "substantially" would overcome the rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims rejection - Ist Paragraph

1. Claims 1-7, 24-26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant broadly claims a method for protecting plant against an environmental stress by transforming with a recombinant protein kinase (PK) domain-containing gene isolated from a plant, transgenic plants and seeds thereof. However, Applicant has disclosed only the PK gene isolated from Arabidopsis thaliana as shown in SEQ ID:1. Applicant has not disclosed PK genes isolated from other plant species. Furthermore, neither the specification

nor the prior art can predict the functional or the structural characteristics of PK genes from other plant species. Subsequently, a person with skill in the art could not have predicted the functional or the structural characteristics of PK genes in transgenic plants. Accordingly, one of skill in the art would not have recognized the applicant to have been in possession of the claimed subject matter at the time the application was filed. As such, this application did not satisfy the written description requirement. To satisfy the written description requirement, Applicants must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the claimed invention.

2. Claims 36-39, 41-46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant broadly claims a substantially pure DNA encoding a PK domain polypeptide isolated from a plant. However, Applicants have disclosed only the PK gene isolated from Arabidopsis thaliana as shown in SEQ ID:1. Applicants have not disclosed PK genes or other substantially pure DNA encoding a PK domain polypeptide isolated from Arabidopsis or other plant species. Furthermore, neither the specification nor the prior art can predict the functional or the structural characteristics of PK genes or other substantially pure DNA encoding a PK domain polypeptide from Arabidopsis or other plant species. As the physical

and structural characteristics of substantially pure DNA encoding a PK domain polypeptide are not disclosed in the specification or known in the prior art, one of skill in the art would not have recognized the applicant to have been in possession of the claimed subject matter at the time the application was filed. As such, this application did not satisfy the written description requirement. To satisfy the written description requirement, Applicants must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the claimed invention.

3. Claims 1-7, 24-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the isolation of PK gene from Arabidopsis thaliana as shown in SEQ ID:1, does not reasonably provide enablement of a method for protecting plant against an environmental stress by transforming with a recombinant protein kinase (PK) domain-containing gene whereby said plants have an increased tolerance to an environmental stress. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The breadth of the claims are not commensurate in scope with the enabling support provided. Applicant broadly claims a method for protecting plant against an environmental stress by transforming with a recombinant protein kinase (PK) domain-containing gene isolated from a plant. However, Applicants have not shown if any DNA molecule would confer tolerance in transgenic plants to environmental stress. Furthermore, Applicants have not

disclosed PK genes isolated from other plant species. Applicants have disclosed only the PK gene isolated from Arabidopsis thaliana as shown in SEQ ID:1. Applicants have not shown if all PK genes have identical nucleotide sequences. The question is then if these nucleotide sequences are different, then the amino acid sequences encoding the PK protein will be different. The specification did not give those skilled in the art guidance as to which amino acids could be changed without losing the enhancing activity of the protein, because a very small change in the amino acid sequence of a protein can result in a very large change in the structure-function. As such, it is unpredictable if the method as claimed will be enabled as a method for protecting a plant against an environmental stress. Thus it is not readily predictable that the genetic modification specifically disclosed will work with other genes or other plants. Applicant has provided no specific guidance as to how to select nucleotide sequences. One wishing to practice the invention is left to proceed through trial-and-error to see what will work and what will not.

In view of the breadth of the claims, unpredictability, lack of guidance in the specification of the results as stated above, it is the examiner' position that one skilled in the art to which it pertains, or with which it is most nearly connected, could not practice the invention commensurate in scope with these claims without undue experimentations.

4. Claims 36-46 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the isolation of PK gene from Arabidopsis thaliana as

shown in SEQ ID:1, does not reasonably provide enablement for the isolation of a substantially pure DNA encoding a PK dominant polypeptide from Arabidopsis or other plant species whereby said DNA confers an increased tolerance to an environmental stress in transgenic plants. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The breadth of the claims are not commensurate in scope with the enabling support provided. Applicant broadly claims a substantially pure DNA encoding a PK dominant polypeptide from Arabidopsis or other plant species whereby said DNA confers an increased tolerance to an environmental stress in transgenic plants. However, Applicant has disclosed only the PK gene isolated from Arabidopsis thaliana as shown in SEQ ID:1. Applicant has not disclosed other PK genes isolated from Arabidopsis or other plant species. Applicant has not taught in the specification, the molecular techniques needed to isolate a substantially pure DNA encoding a PK dominant polypeptide whereby said DNA would confer an increased tolerance to an environmental stress such as dehydration, drought, excess salt. Applicant has not shown if all substantially pure DNA encoding a PK dominant polypeptide would have the same functional property of enhancing the tolerance to an environmental stress or some DNA molecules will be enhancing against excess stress but not drought. Furthermore, if said DNA's are not the same, then the amino acid sequences encoding the PK protein will be different. The specification did not give those skilled in the art guidance as to which amino

acids could be changed without losing the enhancing activity of the protein. Because a very small change in the amino acid sequence of a protein can result in a very large change in the structure-function. As such, it is unpredictable if the substantially pure DNA as as claimed will encode a PK domain polypeptide or will confer an increase in the tolerance to environmental stress. Thus it is not readily predictable that the genetic modification specifically disclosed will work with other genes or other plants. Applicant has provided no specific guidance as to how to select nucleotide sequences. One wishing to practice the invention is left to proceed through trial-and-error to see what will work and what will not.

In view of the breadth of the claims, unpredictability, lack of guidance in the specification of the results as stated above, it is the examiner' position that one skilled in the art to which it pertains, or with which it is most nearly connected, could not practice the invention commensurate in scope with these claims without undue experimentations.

2nd Paragraph

Claims 5, 6, 7, 36, 40 and dependent claims 37-39, 41-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being vague for the recitation of the words " multiple stress conditions". These words are not clearly and concisely defined by the specification. The specification does not provide a standard for

ascertaining the requisite degree of what type of stress condition are involved, how many and if all of these stress conditions are taking place at the same time, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The meaning of these words in the context of these claims is not clear, and the specification fails to define or clarify the use of these words.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being vague for the recitation of the words " activates the expression of a stress-protective protein". These words are not clearly and concisely defined by the specification. It s not clear if PK gene when overexpressed or underexpressed will activate the expression of a stress-protective protein, or if changes in the amino acid sequence will take place to make it activates the expression of a stress-protective protein.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being vague for the recitation of the words " constitutively expressed". These words are not clearly and concisely defined by the specification. It is not clear if the gene will be constitutively expressed under a promoter, without promoter, under enhancer element or an intron, by mutation or will be expressed constitutively only during the stress.

Claims 36, 40 and dependent claims 37-39, 41-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for the recitation of the word " substantially". The word is not clearly and concisely defined by the specification. " Substantially" is a broad term

and it is indefinite in that it fails to point out what is included or excluded by the claim language and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 36-46 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Urao et al [Mol. Gen. Genet. 1994. 244: 331-340].

The claims are directed to a substantially pure DNA encoding a PK dominant polypeptide, and host cell thereof whereby said DNA is expressed under control expression region.

The reference teaches nucleotide and deduced amino acid sequences of two cDNAs, cATDPK 1 and cATDPK2 isolated from Arabidposis plants which appear to be identical to the nucleotide sequence disclosed in SEQ ID:1 (Figure 3A,B, page 334; see also Materials and Methods, paragraph 3-5, page 332). The DNA molecule cATDPK2 disclosed by the reference is a 1.7-Kb Bam H1 fragment containing the full length cDNA which was cloned into the BamHI site of pGEX-1 vector (lines 1-2, last paragraph of column 1, page 332) under

a promoter that is induced constitutively in the presence of IPTG (lines 10-12, column 1, page 333) which was transformed into E. coli JM109 cells (lines 3-4, page 333). The DNA molecule taught by the reference appears to be identical to the substantially pure DNA encoding a dominant polypeptide as claimed because it appears to possess the same functional and structural characteristics (e.g., a DNA encoding a PK domain polypeptide, involved in regulation of drought and high salt stress). The production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when the properties of the product are not changed by the process in an expected manner. See In re Thorp, 227 USPQ 964 (CAFC 1985); In re Marosi, 218 USPQ 289, 29222-293 (CAFC 1983); In re Brown, 173 USPQ 685 (CCPA 1972). Since the Office does not have the facilities for examining and comparing applicants' DNA molecule with the DNA molecule of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., the DNA molecule of the prior art does not possess the same material structural and functional characteristics of the claimed DNA molecule). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594. Additionally, characteristics such as the ability to enhance tolerance to environmental stress would be inherent in DNA molecule of the prior art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) a patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1-7, 24-26 are rejected under 35 U.S.C 103 (a) as being unpatentable over Urao et al [Mol. Gen. Genet. 1994. Vol. 244: 331-340] taken with Gordon-Kamm et al (The Plant Cell. 1990. Vol. 2: 603-618).

The claims are drawn to a method for protecting plant against an environmental stress by transforming with a recombinant protein kinase (PK) domain-containing gene whereby said plants have an increased tolerance to an environmental stress, transgenic plants and seeds thereof.

Urao et al teach a method for the isolation of nucleotide and deduced amino acid sequences of two cDNAs, cATDPK 1 and cATDPK2. The DNA sequences include the putative coding regions and the 5'-and 3'-noncoding regions (Figure 3A,B, page 334; see also Material and methods, paragraph 3-5, page 332). The reference teaches that said genes function in the modulation of drought tolerance (paragraph 2 in column 1 and paragraph 1 in column 2, page 338).

Urao et al does not teach specifically, a method for inserting the gene into transgenic plants.

Gordon-Kamm et al. teach a method for inserting the heterologous gene into transgenic plants whereby said gene is constitutively expressed under a constitutively expressing CaMV 35 promoter (Figure 1, page 604, paragraph 1, page 615). Transgenic plants taught by the reference produced transgenic seeds (Figure 9, page 611).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify the process of Gordon-Kamm by incorporating the gene taught by Urao et al in order to develop a method for producing transgenic plants that are tolerant to environmental stress (e.g., drought tolerance) as claimed. The teachings of Urao et al and Gordon-Kamm are combinable because they are from a similar problem solving area e.g., plant gene expression and transformation. The motivation for doing so would have been to use genes taught by Urao et al to produce transgenic plants that are tolerant to environmental stress.

Therefore, it would have been obvious to combine the teachings Urao et al and Gordon-Kamm et al. to obtain a method for protecting plant against an environmental stress by transforming with a recombinant protein kinase (PK) domain-containing gene whereby said plants have an increased tolerance to an environmental stress as claimed. Said transgenic

plants are expected to be tolerant to other types of stresses such as salt, dehydration, and temperature the mechanisms of resistance to theses stresses share many common pathways. Thus the claimed invention would have been prima facie obvious as a whole to one of ordinary skill in the art at the time the invention was made, especially in absence of evidence to the contrary.

2. Claims 36-46 are rejected under 35 U.S.C 103 (a) as being unpatentable over Urao et al [Mol. Gen. Genet. 1994. Vol. 244: 331-340] taken with Gordon-Kamm et al (The Plant Cell. 1990. Vol. 2: 603-618).

The claims are directed to a substantially pure DNA encoding a PK dominant polypeptide, and host cell thereof whereby said DNA is expressed under control expression region whereby host cells have an increased tolerance to environmental stress.

Urao et al teach nucleotide and deduced amino acid sequences of two cDNAs, cATDPK 1 and cATDPK2. The DNA sequences include the putative coding regions and the 5'-and 3'-noncoding regions (Figure 3A,B, page 334; see also Material and methods, paragraph 3-5, page 332). The reference teaches that said genes function in the modulation of drought tolerance (paragraph 2 in column 1 and paragraph 1 in column 2, page 338).

Urao et al do not teach, specifically, a transgenic plant or a method for inserting the gene into transgenic plants.

Gordon-Kamm et al. teach a transgenic plant that expresses a heterologous gene (Figure 9, page 611). The reference teaches a method for inserting the heterologous gene into transgenic plants whereby said gene is constitutively expressed under a constitutively expressing CaMV 35 promoter (Figure 1, page 604, paragraph 1, page 615).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify the process of Urao et al to isolate other DNA molecules which encode a PK dominant protein using the polymerase Chain Reaction (PCR) as taught by Urao et al (second paragraph, column 2, page 332). Furthermore, it would have been obvious to modify the process of Gordon-Kamm by incorporating the gene taught by Urao et al in order to produce transgenic plants that are tolerant to environmental stress (e.g., drought tolerance) as claimed. The teachings of Urao et al and Gordon-Kamm are combinable because they are from a similar problem solving area e.g., plant gene expression and transformation. The motivation for doing so would have been to use genes taught by Urao et al to produce transgenic plants that are tolerant to environmental stress.

Therefore, it would have been obvious to combine the teachings Urao et al and Gordon-Kamm et al. to obtain protected plants against an environmental stress by

transforming with a recombinant protein kinase (PK) domain-containing gene whereby said plants have an increased tolerance to an environmental stress as claimed. Said transgenic plants are expected to be tolerant to other types of stresses such as salt, dehydration, and temperature beacuse the mechanisms of resistance to these stresses share many common pathways. Furthermore, the DNA molecule disclosed by Urao et al appears to be identical in functional and structural characteristics to that taught in the specification, and subsequently the DNA of the prior art is expected to have the same functional property. The use of inducible promoters or other expression regulatory regions would be a matter of choice unless the proof of criticality is provided. Thus the claimed invention would have been prima facie obvious as a whole to one of ordinary skill in the art at the time the invention was made.

CONCLUSION

No claims are allowed.

Future Correspondence

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Ousama M-Faiz Zaghmout whose telephone number is (703) 308-9438. The Examiner can normally be reached Monday through Friday from 7:30 am to 5:00 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, L. Smith, can be reached on (703) 308-3909. The fax phone number for the group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to THE MATRIX CUSTOMER SERVICE CENTER whose telephone number is (703) 308-0196.

Ousama M-Faiz Zaghmout Ph.D.
September 5, 1999